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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/505,458 | 02/11/2000 | Michael R. Rosen | 61020-A/HOW/PJP | 6325 |

7590 09/17/2003

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| EXAMINER | |
|---|---|
| OROPEZA, FRANCES P | |
| **ART UNIT** | **PAPER NUMBER** |
| 3762 | 25 |

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/505,458 | ROSEN ET AL. | |
| | Examiner | Art Unit | |
| | Frances P. Oropeza | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *8/4/03 (Amendment)* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *24* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Response to Amendment*

1. The Applicant's amendments to the claims filed 8/4/03 overcome the rejection of record hence a new rejection is established in the subsequent paragraphs. Since much of the new rejection reflects the previous rejection, the Applicant's arguments are addressed below.

### *Claim Rejections - 35 USC § 102*

2. Claims 1, 9-11, 20, 28-30, 39 and 47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Ben-Haim et al. (US 6363279).

Ben-Haim et al. teach a method of modifying the force of contraction of a heart by applying a non-excitatory electrical field (col. 1 @ 31-45) to modify/ alter/ remodel the action potentials, the ionic pumps and the channels of the heart (col. 2 @ 6 – col. 3 @ 32), hence preventing arrhythmias such as ventricular fibrillation (col. 8 @ 41-48).

The channels that connect the heart, read to include gap junction channels, are modified/ remodeled by electrical stimulation (col. 2 @ 6 – col. 3 @ 32; col. 27 @ 12-27 and 52-57; col. 31 @ 1-5). While the gap junction channels are not specifically mentioned when Ben-Haim addresses the channels of the heart, it is inherent that the Ben-Haim et al. invention controls the gap junction channels as they are an essential component of the heart conduction system as noted in the record by Winslow et al. (US 5947899) (col. 5 @ 28 – col. 6 @ 3; col. 6 @ 33-53).

Refractory periods are modified by electrical stimulation (col. 8 @ 3-5; col. 47 @ 37-45; col. 8 @ 66 – col. 9 @ 3; col. 9 @ 15-19; col. 17 @ 26-35; col. 17 @ 45-46; col. 31 @ 26-31).

Ion channels are modified by electrical stimulation (col. 26 @ 62 – col. 27 @ 27; col. 27 @ 43-57; col. 31 @ 1-5).

Mechanical and electrical changes in the heart occur over time as the heart is altered/ remodeled (col. 9 @ 51-55; col. 38 @ 48 – col. 39 @ 10). Electrodes can be attached by sewing (col. 30 @ 9-12). Electrodes can be placed in the heart or in vessels (col. 37 @ 30-35; col. 40 @ 48-51). Electrodes can be activated in pairs (col. 37 @ 15-17).

The Applicant's arguments filed 8/4/03 have been fully considered, but they are not convincing.

The Applicant argues Ben-Haim et al. does not teach exciting the heart, resulting in remodeling of gap junctions, alter the effective refractory periods, or inducing ion channel remodeling. The Examiner disagrees. Ben-Haim et al. teach the heart is controlled/ altered/remodeled using electrical stimulation (col. 1 @ 26-27), hence modifying the action potentials, the ionic pumps and the channels of the heart (col. 2 @ 6 – col. 3 @ 32). As to gap junction channels, the channels that connect the heart are remodeled using electrical stimulation; the channels are read to include gap junction channels (col. 2 @ 6 – col. 3 @ 32; col. 27 @ 12-27 and 52-57; col. 31 @ 1-5). While the gap junction channels are not specifically mentioned when Ben-Haim addresses the channels of the heart, it is inherent that the Ben-Haim et al. invention controls the gap junction channels as they are an essential component of the heart conduction system as noted in the record by Winslow et al. (US 5947899) (col. 5 @ 28 – col. 6 @ 3; col. 6 @ 33-53). As to refractory periods, refractory periods are altered by electrical stimulation (col. 8 @ 3-5; col. 47 @ 37-45; col. 8 @ 66 – col. 9 @ 3; col. 9 @ 15-19; col. 17 @ 26-35;

col. 17 @ 45-46; col. 31 @ 26-31). As to ion channels, ion channels are remodeled by electrical stimulation (col. 26 @ 62 – col. 27 @ 27; col. 27 @ 43-57; col. 31 @ 1-5).

The Applicant argues that since Ben-Haim et al. only changes the muscle mass of the heart over time, changing muscle mass does not necessarily result in remodeling the gap junction, altering the refractory period in the heart or inducing the ion channel remodeling. The Examiner disagrees. Ben-Haim et al. disclose methods to control and change the electrical and mechanic activity of the cardiac muscle cells that produce changes the muscle mass and changes in the action potential plateau duration, the activation time, the activation sequence, the contractability and the conduction pathways of the cardiac segment, hence Ben-Haim is read to remodel gap junctions, alter the heart refractory period and induce ion channel remodeling (col. 2 @ 6 – col. 3 @ 32; col. 7 @ 65-67; col. 34 @ 28-34).

The Applicant asserts the Examiner interprets "ion channels" to include "gap junctions". The Examiner disagrees. The Examiner recognizes "ion channels" and "gap junctions" are different physiological entities.

In response to the applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., claim 20, 30 and 59 – "the refractory period is altered, and remains altered after the external stimulation is removed") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Applicant argues Ben-Haim et al. only provides change and control of the cardiac processes in a current moment or until electrical stimulation ceases. The Examiner disagrees.

Ben-Haim et al. apply stimulation to create cardiac process changes in the current moment. In addition, Ben-Haim et al. recognize applying electrical stimulation in the current moment produces long-term/ permanent changes of the cardiac processes, read as remodeling and altering of the cardiac processes. These long-term changes are reflected in a need for the therapy to be altered periodically and are reflected when treatment targets are met and the therapy is discontinued because the cardiac process has been changed to the point that therapy is no longer needed, hence Ben-Haim et al. disclose changes in the cardiac process in the moment and long-term (col. 9 @ 15-19; col. 9 @ 51 – col. 10 @ 3; col. 30 @ 34-37; col. 34 @15-38; col. 35 @ 55-59; col. 38 @ 48 – col. 39 @ 18).

***Claim Rejections - 35 USC § 103***

3. Claims 2, 5, 12, 13, 15, 21, 24, 31, 32, 34, 40, 43, 50, 51, 53 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (US 5681308).

As discussed in paragraph 2 of this action, Ben Haim et al. disclose the claimed invention except for the 7cm x 1 cm (claims 4, 23 and 42) strip (claims 2, 13, 21, 32, 40 and 51) of electrode material having linked multiple electrode pairs, where the pairs are arranged in two columns (claims 12, 31 and 50) with one electrode in each pair in one column and the other electrode in each pair in the other column (claims 5, 15, 24, 34, 43, 53 and 58-60).

Edwards et al. disclose an analogous mapping apparatus and teach that it is known to use a circuit (38) mounted on a membrane support (16) to serve as a cardiac electrode which provides columns of individually controlled treatment electrodes (34) which can be multiplexed

to enable stimulation of electrode pairs (figure 7; col. 7 @ 38-52). Absent any teaching of criticality or unexpected results, it is understood the electrode can be configured as a 7cm x 1 cm strip with only two columns of electrodes. The configuration change is an obvious change in shape based on the specific application. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the electrode as taught by Edwards et al. to provide a flat electrode with multiple electrode measurement and stimulation configurations so the cardiac tissue can be more effectively treated.

4. Claims 3, 4, 14, 17-19, 22, 23, 33, 36-38, 41, 42, 52 and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (5681308) and further in view of Dahl et al. (US 5203348).

As discussed in paragraphs 2 and 3 of this action, modified Ben-Haim et al. disclose the claimed invention except for:

- the electrode strip of polyurethane (claims 3, 14, 22, 33, 41, and 52),
- the electrode comprised of platinum or consisting essentially of unalloyed platinum (claims 17-18, 36-37 and 55-56 ), and
- the electrode connected to insulated stainless steel wire (claims 19, 38 and 57).

Dahl et al. disclose an electrode and teach that it is known to fabricate an electrode with a platinum or platinum alloy conductor or conductor with a stainless steel core (col. 5 @ 19-36), and a lead with a medical grade polyurethane sheath and a stainless steel coated conductor

(col. 5 @ 23-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the materials of construction as taught by Dahl et al.. One have ordinary skill in the art would have been motivated to make such a modification in electrode to specify materials of construction that have proven electrical properties.

5. Claims 7, 8, 26, 27, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Dahl et al. (US 5203348).

As discussed in paragraph 2 of this action, Ben-Haim et al. disclose the claimed invention except for the electrode being platinum or consisting essentially of unalloyed platinum.

Dahl et al. disclose an electrode and teach that it is known to fabricate an electrode with a platinum or platinum alloy conductor (col. 5 @ 23-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the platinum of platinum alloy conductor as taught by Dahl et al.. One have ordinary skill in the art would have been motivated to make such a modification in electrode to specify materials of construction that have proven electrical properties.

6. Claims 6, 16, 25, 35, 44 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US 6363279) in view of Edwards et al. (US 5681308) and further in view of Ideker (US 5873896).

As discussed in paragraphs 2 and 3 of this action, modified Ben-Haim et al. disclose the claimed invention except for the electrode pair being 2mm from each other and the electrode pairs being spaced at least 5 mm apart.

Idecker teaches a cardiac device for reducing arrhythmias and teaches that it is known to use an electrode configuration of an elongate primary strip with a plurality of electrodes positioned at spaced intervals, e.g. 1-4 millimeters (col. 3 @ 2-4). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method for modifying the force of contraction of a heart as taught by Ben-Haim et al., with the electrode spacing as taught by Ideker to provide electrode spacing known to effectively reduce cardiac arrhythimias.

***Statutory Basis***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Conclusion***

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, telephone number (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

9/13/03

Angela D. Sykes

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